One Source Toxicology Laboratory, Inc.
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February 16, 2004

US Food and Drug Administration
Division of Dockets Management (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20852

Re: Docket No. 2003D-0522

Dear FDA Staff:

The management and staff of One Source Toxicology Laboratories, Inc., a wholly owned subsidiary of Employer Support Services, Inc. (ESSI), a privately held corporation located in Houston, TX, wishes to express our comments concerning the above mentioned Docket regarding Over the Counter (OTC) Screening Tests for Drugs of Abuse.

As a SAMHSA certified laboratory, acquired four years ago from the University of Texas Medical Branch (UTMB) Galveston and relocated to Houston, TX, we perform an average of 2,000 drug screens per day (two shifts) for detection of drugs of abuse and are approaching 500,000 screens per year.

Nationwide, approximately 5,000 clients contract with our laboratory to perform urine drug screens and confirmation of positives. Our customers include large corporations, government agencies, small business owners, industry consortiums, schools, and concerned parents.

Additionally, our laboratory performs drug tests for a number of Third Party Administration (TPA) companies that administer Substance Abuse Programs for an even greater number of their clients in the workplace.

The management and staff of our laboratory, whose combined personal years of experience in the drug testing industry would easily exceed 50 years, wish to express our "real world" opinions and observations with regards to OTC On-site drug testing kits.

Please consider the following matters of record and observation:

1) Many of our clients use OTC On-site Kits and forward positive specimens only to our laboratory for a confirmation. Our Responsible Person (RP) and certifying scientist can document that just under 40% of these positive kit specimens are false-positive based on our SAMHSA certified confirmations. One can only

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speculate as to the massive number of false-negatives that occur in the workplace based on the errors found on positive results. We direct you to an evaluation performed by SAMHSA of non-instrumental drug test devices (copy of which is attached to this writing) that has documented results showing as high as 65% false positive and false negative results from a sampling of OTC drug test kits purchased in the market place. Kits with such a diversion of results and margin-of-error becomes an absolute mockery of science and an embarrassment to our industry.

2) As a laboratory we track positive rates on submitted specimens. In the opinion of our staff, the positive rate found using "kits" in the field rarely, if ever, approached the rate found using a laboratory, especially with kits showing a 40% false-positives rate. Further, in many cases the cut-off levels for drugs using the kits may not meet contractual specifications (cut-off levels) of the client, the government agency, or the bid specifications for the job.

3) The State of Nevada, as well as a number of other States, has basically "outlawed" the use of on-site kits in the workplace; instead, requiring all drug tests performed by employers to be conducted by a laboratory. This ruling was based on sound reasoning, we can be sure, and the FDA should take note.

4) By using OTC On-site kits the due process of a Medical Review Officer (MRO) is minimized. The kit generally reduces the privacy/confidentiality of the donor. The dependability of a forensic chain-of-custody documentation is greatly diminished, in that the paperwork cannot be depended upon, thereby greatly reducing accurate record keeping.

5) In our efforts to procure business, often we are confronted with business owners or heads of government agencies who believe they operate proper drug testing programs simply because they've purchased a few kits and stocked them on their shelves in a personnel office somewhere. In too many cases these kits haven't been used for years. When used, the kits are administered by untrained personnel, i.e. construction supervisors, office staff, owner's wives, secretarial help, etc. In effect, the kits become an inappropriate excuse for claiming a responsible Drug-testing Program, and in the process, proper protocols and measures taken to ensure a drug-free workplace are totally disregarded. As professionals, we've developed a general mistrust of these on-site kits and view them as a liability of *massive* proportions for all parties concerned. In other words, most of the industry's so-called "short-cuts", missed offenders, oversights, inside bribes, and inefficiencies found in substance abuse testing seem to be surrounded around these on-site kits. A Medical Technician is required to perform the test (tests are rated as moderately difficult), but, as a rule, test kits are not performed by someone qualified, let alone someone protected through a Hepatitis B Vaccination (OSHA requirement). Individuals performing these tests are required little or no training or educational experience.

6) As for the "economics" of on-site kits, a case can easily be made that after the costs of the kits, the laboratory confirmations of positives only and the cost of an MRO divided by the number of tests a total price per test using on-site kits will exceed the cost of a certified laboratory cost per test.

RESOURCES AND TOOLS

Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention
Division of Workplace Programs

Subject: An Evaluation of Non-Instrumented Drug Test Devices

Date: January 29, 1999

Note: A printed copy of this report may be obtained by contacting the Division of Workplace Programs, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857, Phone: 301-443-6014, Fax: 301-443-3031, email: wvogl@samhsa.gov

Background

The Department of Health and Human Services (HHS) published in the Federal Register on April 11, 1988, the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The Mandatory Guidelines detail comprehensive standards for laboratory procedures, specified drugs for which Federal employees can be tested, and established appropriate standards and procedures for periodic review of laboratories and criteria for certification of laboratories engaged in urine drug testing for Federal agencies. The Mandatory Guidelines were revised on June 9, 1994, but the basic requirement for laboratory testing was not changed. In addition to covering the testing of Federal employees in the Executive Branch of the Federal government, the Department of Transportation requires its regulated industries to use HHS certified laboratories.

During the past few years, there has been a rapid expansion in the private sector to test for the presence of illicit drugs in other biological specimens (such as, sweat, oral fluid, and hair) as well as the use of on-site urine drug test devices. Approximately 2 years ago, the Division of Workplace Programs (DWP) began a review of the testing of alternative specimens and the use of on-site test devices. As part of the review, DWP funded Duo Research, Incorporated, to conduct a study to evaluate the performance of on-site drug test devices currently being marketed. This study was actually a second study of 15 new or modified on-site test devices that had been originally evaluated for the Administrative Office of the U.S. Courts in 1996. As in the first study, this study focused on the testing of specimens clustered above and below the cutoffs, specimens that were clearly negative or positive, and known quality control samples.

This study is not intended to make recommendations for specific products, but to provide a general assessment of the performance of currently available non-instrumented drug test devices.

Device Evaluation

All known non-instrumented drug test manufacturers and device distributors were contacted to obtain devices. Of these, 15 devices were provided by the manufacturers or distributors. A Behring Diagnostics' ETS instrument using Emit d.a.u. reagents served as a reference device. Other available instrumented systems were not included in the study.

The study was designed to test each device with 90 selected clinical specimens and 10 control samples for each drug. The specimens were selected from routine specimens submitted by Federal Probation Offices to PharmChem Laboratories under its contract with the Administrative Office of the U.S. Courts. They had been tested on an Hitachi 747 analyzer using Diagnostic Reagents, Inc (DRI) enzyme immunoassay test kits. The immunoassay rate data were compared to spiked control values to classify specimens into four categories: negative, below cutoff (ranging from about 25% below cutoff to cutoff), above cutoff (ranging from cutoff to about 25% above the cutoff), and high (greater than 25% above the cutoff). Approximately 60 specimens had responses in the below and above cutoff categories. Specimens testing negative were selected and stored frozen until needed. Positive specimens were selected from previously confirmed positives that were ready for disposal. For phencyclidine, a sufficient number of unique clinical specimens in the desired range was not available, so dilutions (with negative urine) of positive clinical specimens were performed. The accuracy of these dilutions was checked on the ETS prior to inclusion in the study and by gas chromatography/mass spectrometry (GC/MS) following the study.

Each day, 20 to 30 specimens for a given drug were thawed and tested on all the study devices. Specimens were identified to

the operators only by bar coding. All devices in this study indicate a negative result by the appearance of a colored line at the area designated for each drug. Positive results are indicated by the absence of a line.

The performance of the devices was assessed in terms of their "Positive Predictive Values" (PPV) and "Negative Predictive Values" (NPV) and percentages of false positive and false negative results. These are standard analytical measures of the certainty of obtaining a correct positive and negative result, respectively. Thus, a high percentage or high PPV indicates that there is a high certainty that a positive result from the device will be confirmed as positive, or as negative for a high NPV.

This differs from the percentage of true positives, called sensitivity, and percentage of true negatives, called specificity. These measures indicate the percentage of all specimens confirmed positive by GC/MS that were identified as positive by the device, or of those confirmed as negative by GC/MS that were negative by the device. Also, specimens confirmed as positive but identified as negative by the device are false negative results, and for specimens confirmed as negative but identified as positive by the device are false positive results. The combination of all correct negative and positive results represents an estimate of the overall accuracy for both positive and negative results for each device.

The definitions used for this study are given below. Tables 1 through 5 show the PPV, NPV, and accuracy data for each test device versus GC/MS at the HHS cutoffs and with all borderline readings scored as negative (many devices give equivocal results, which were scored initially as "borderline") for each drug. Table 6 gives the combined results for all drugs for each test device. Figures 1 through 5 are the bar-graphs showing the sensitivity, false negatives, false positives, and specificity as percentages for each drug class for each test device ("PD" is used to represent the performance of a "Perfect Device"). Figure 6 gives the combined results for all drugs for each test device. It must be noted that the results for opiates were based on the 300 ng/mL cutoffs. None of the specimens included in the study would have been positive at 2,000 ng/mL.

Note: Codes have been used in the tables and figures contained in this report to conceal the identities of the test devices. However, each manufacturer has received a report that identifies the results for its test device.

The evaluation of the 15 devices was conducted with a majority of the specimens grouped around the screening cutoffs. It was found, as expected, that many devices gave a fair number of false positive and false negative results. It is also expected, based on experiences in the field, that specimens encountered in most Workplace testing situations will have fewer specimens with drug concentrations near the cutoff. This means that a much higher percentage of confirmed positive results and fewer false negative results should occur during actual testing in the field.

The favorable performance of the devices was encouraging considering the simplicity of their design and operational requirements. Some devices were able to identify more positive specimens, but this was accompanied by a higher percentage of false positive results. Other devices were more conservative, giving few false positive results but missing many true positives.

Test Devices Evaluated

Dipro 10 Panel

Each device is packaged in a sealed pouch. The device consists of a flat plastic card that has five dipsticks extending from one edge. Two of these are connected back-to-back providing for ten separate test strips. The strips are covered with a protective cap. Storage does not require refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations and areas for donor ID and date. The device includes a "control" or validity check. The test requires the removal of the cap, insertion of the dipsticks into the specimen for about 10 seconds. The cap can be replaced. The endpoint for a positive results if the absence of a line at the test band windows. Manufactured by American Biomedical, Inc.

Distributor: Dipro Diagnostics
3415 Hycliffe Avenue
Louisville, KY 40207
Phone: 502-899-3108

Drug Check Cup

Each device is packaged in a sealed bag. Expiration dates are stamped on the bags. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The device is a self-contained collection and storage cup, that has the drug test strips imbedded in its side. The cup is closed with a screw-cap lid after specimen collection. The test begins as soon as the urine is added to the cup. There is no other activation step required. Results can be read within 5 to 9 minutes. The endpoint for a positive result is the absence of a line at the test band.

Distributor: Job Services, Inc.
32107 West Lindero Canyon Road

Westlake Village, CA 91361
Phone: 818-599-2512

Dtx 520

Each cassette-style device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The test requires the addition of 4 to 5 drops of urine to a well at one end of the device. Results can be read within 3 to 8 minutes, but should be read within 8 minutes. The endpoint for a positive results is the absence of a line at the test band. Manufactured by Forefront Diagnostics, Inc.

Distributor: Universal Drug Testing Company
467 Route 51
Large, PA 15025
Phone: 888-822-7120

Genie Cup

Each device is packaged in a sealed bag. Expiration dates are stamped on the bags. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The device is a self-contained collection and storage cup, that has the drug test strips imbedded in its side. The cup is closed with a screw-cap lid after specimen collection. At the time of testing, the lid is turned to its fully closed position. This depresses a plunger to trap a portion of the specimen in the test chamber. Results can be read as soon as a line appears in the "test valid" area. The endpoint for a positive result is the absence of a line at the test band. Timing is said not to be important. Manufactured by American Biomedical, Inc.

Distributor: Point of Care Technologies
6 Taft Court, Suite 150
Rockville, MD 20850
Phone: 888-713-8700

InstaCheck

Each cassette-style device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The test requires the addition of 4 to 5 drops of urine to a well at one end of the device. Results can be read within 3 to 8 minutes, but should be read within 8 minutes. The endpoint for a positive result is the absence of a line at the test band. Manufactured by Forefront Diagnostics, Inc.

Distributor: Forefront Diagnostics, Inc.
23561 Ridge Route Drive, Suite D
Laguna Hills, CA 92653
Phone: 949-595-0673

PharmScreen Drug Screen Card

Each device is packaged in a sealed pouch. The device consists of a flat card that has five dipsticks extending from one edge. The strips are covered with a protective cap. Storage does not require refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear designations and areas for donor ID and date. The device includes a "control" or validity check. The test requires the removal of the cap, insertion of the dipsticks nto the specimen for about 10 seconds. The cap can be replaced. The endpoint for a positive result is the absence of a line at the test band windows. Manufactured by American Biomedical, Inc.

Distributor: PharmChem Laboratories, Inc.
1505A O'Brien Drive
Menlo Park, CA 94025
Phone: 800-446-5177

PharmScreen Drug Screen Multi

Each cassette-style device is packaged in a sealed pouch. Storage does not require refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations and areas for donor ID and date. The device includes a "control" or validity check. The test requires the addition of 4 to 5 drops of

urine to a well at one end of the device. ılts can be read within 3 to 8 minutes, b hould be read within 8 minutes. The endpoint for a positive result is the absence of a line at the test band windows. Manufactured by American Biomedical, Inc.

Distributor: PharmChem Laboratories, Inc.
1505A O'Brien Drive
Menlo Park, CA 94025
Phone: 800-446-5177

Rapid Drug Screen

The device is a cup and a separate card containing the individual test strips. It is packaged in a sealed pouch. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations and areas for donor ID and date. The device includes a "control" or validity check. The test requires the insertion of the test card through a slit in the lid and into the specimen. Results can be read within 3 minutes, but should be read within 8 minutes. The endpoint for a positive result is the absence of a line at the test band windows. Manufactured by American Bio Medica Corporation.

Distributor: Integrated Corporate Solutions, Inc.
3121 Sunnybrook Road
Mogadore, OH 44260
Phone: 330-677-2441

Status DS-5

Each cassette-style device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but 35° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The test requires the addition of 3 drops of urine to a well at one end of the device. Results can be read within 3 to 5 minutes, but should be read within 10 minutes. The endpoint for a positive result is the absence of a line at the test band. Manufactured by Princeton BioMeditech.

Distributor: Orion Diagnostica, Inc.
71 Veronica Avenue
Somerset, NJ 08873
Phone: 800-526-2125

Syva Rapid Test

Each cassette-style device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but 35° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The test requires the addition of 3 drops of urine to a well at one end of the device. Results can be read within 3 to 5 minutes, but should be read within 10 minutes. The endpoint for a positive result is the absence of a line at the test band. Manufactured by Princeton BioMeditech.

Distributor: Dade Behring, Inc.
3403 Yerba Buena Road
San Jose, CA 95135
Phone: 800-729-7982

TesTcup 5

Each device is packaged in a sealed bag. Storage does not require refrigeration, but 65° to 85°F is recommended. Expiration dates are stamped on the bags. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The device is a self-contained collection and storage cup, that has the drug test strips imbedded in its side. The cup is closed with a screw-cap lid after specimen collection. At the time of testing, the lid is turned to its "test"position, the cup tilted until the urine covers 1/2 to 3/4 of the lid (do not invert fully). It is held in this position for 10 seconds, then returned to its upright position. Results can be read as soon as the "TEST VALID" window develops a blue color, usually within 5 minutes. The endpoint for a positive result is the absence of a line at the test band. Timing is said not to be important. An adhesive covering strip is removed from the test display windows and placed on a small "breather" hole on the back of the cup. The lid should then be returned to the sealed position if the specimen is to be stored or sent for confirmation. Manufactured by Roche Diagnostic Systems, Inc.

Distributor: Roche Diagnostic Systems, Inc.
1080 U.S. Highway 202
Somerville, NJ 08876-3771

Phone: 800-526-1247

Accutest

Each cassette-style device is packaged in a sealed pouch with an attached pipette. Storage does not required refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The test requires the addition of urine from a pipette marked for about 0.2 mL to a well at one end of the device. Results can be read within 3 to 8 minutes, but should be read within 8 minutes. Manufactured by Jant Pharmacal Corporation.

Distributor: Jant Pharmacal Corporation
16255 Ventura Boulevard, Suite 505
Encino, CA 91436
Phone: 818-986-8530

One Step

Each device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but can be if desired, or a room temperature, 65° to 85°F. Expiration dates are stamped on the pouches. The devices are well labeled. The device includes a "control" or validity check. The test is in the form of a dipstick, requiring the dipping of the strip into the urine, preferably a small aliquot in a test tube. Results can be read within 3 minutes, but must be read within 5 minutes. The endpoint for a positive result is the absence of a line at the test band. Manufactured by Technical Chemicals & Products, Inc.

Distributor: Technical Chemicals & Products, Inc.
P.O. Box 9748
Ft. Lauderdale, FL 33310
Phone: 954-979-0400

QuickScreen

Each cassette-style device is packaged in a sealed pouch with an attached pipette. Storage does not required refrigeration, but 40° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled. The device includes a "control" or validity check. The test requires the slow addition of 4 drops of urine to a well at one end of the device. Results can be read within 10 minutes. The endpoint for a positive result is the absence of a line at the test band. Manufactured by PhamaTech.

Distributor: PhamaTech
9265 Activities Road
San Diego, CA 92126
Phone: 619-635-5840

TesTstik

Each device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled. The device includes a "control" or validity check. The test requires the dipping of the device into a urine samples up to a mark on the device for 5 to 7 seconds. Results can be read within 5 minutes, but should not be read after 30 minutes. The endpoint for a positive results is the absence of a line at the test band. Manufactured by Roche Diagnostic Systems, Inc.

Distributor: Roche Diagnostic Systems, Inc.
1080 U.S. Highway 202
Somerville, NJ 08876-3771
Phone: 800-526-1247

Definitions

True Positive (TP)

A positive result by the test device and a positive result by GC/MS (the reference method).

False Negative (FN)

A negative result by the test device and a positive result by GC/MS.

False Positive (FP)

A positive result by the test device and a negative result by GC/MS. This includes both "unconfirmed" positives, i.e., samples with drugs present below the cutoff and samples with no drugs detected.

True Negative (TN)

A sample negative by the test device and negative by GC/MS.

Sensitivity

The number of True Positive results for a test device out of all GC/MS positives in the study expressed as a percentage (TP x 100/(TP + FN)).

Specificity

The number of True Negative results for a test device out of all GC/MS negatives in the study expressed as a percentage (TN x 100/(TN +FP).

Prevalence

The percentage of positive specimens in a given population of specimens.

Positive Predictive Value (PPV)

The probability that a positive result for a test device will be a True Positive in a population with a known or estimated prevalence of positive specimens (that is, a value calculated for a device as to its ability to produce correct positive results, which is dependent upon the prevalence of positive specimens).

PPV = [Sensitivity x Prevalence] / [(Sensitivity x Prevalence) + ((1 - Prevalence) x (1 -Specificity)]

Negative Predictive Value (NPV)

The probability that a negative result for a test device will be a True Negative in a population with a known or estimated prevalence of positive specimens (that is, a value calculated for a device as to its ability to produce correct negative results which is dependent upon the prevalence of positive specimens).

NPV = [Specificity x (1 - Prevalence)] / [((1 - Sensitivity) x Prevalence) + (Specificity x (1 - Prevalence))]

Table 1. PPV, NPV, and Accuracy Values for Test Results versus GC/MS using HHS Cutoffs (All borderline results as negative)

Amphetamines

Device	PPV	NPV	Accuracy
Perfect Device	1.000	1.000	1.000
Ja	0.818	0.873	0.867
Ga	0.786	0.895	0.878
Da	0.714	0.942	0.889
La	0.556	0.827	0.800

Ea	0.545	0.896	0.809
Aa	0.500	0.981	0.789
Ha	0.476	0.870	0.778
Nm	0.467	0.840	0.778
Ca	0.432	0.943	0.733
Nm	0.400	0.843	0.744
Km	0.360	0.846	0.711
Bam	0.327	0.947	0.589
Pm	0.313	0.811	0.722
Lm	0.281	0.828	0.633
Im	0.278	0.833	0.611
Fam	0.267	0.841	0.551
Dm	0.258	0.814	0.622
Cm	0.213	0.793	0.400
Qm	0.091	0.772	0.689

Note: "a" is amphetamine specific, "m" is methamphetamine specific, "am" is sensitive to both amphetamines

Table 2. PPV, NPV, and Accuracy Values for Test Results versus GC/MS using HHS Cutoffs (All borderline results as negative)

Cannabinoids

Device	PPV	NPV	Accuracy
Perfect Device	1.000	1.000	1.000
P	1.000	0.474	0.556
H	0.935	0.576	0.700
B	0.933	0.567	0.689
E	0.848	0.544	0.656
M	0.833	0.556	0.667
D	0.810	0.583	0.689
N	0.784	0.641	0.722
J	0.774	0.649	0.722

I	0.757	0.509	0.611
G	0.721	0.773	0.733
Q	0.705	0.500	0.600
L	0.697	0.929	0.733
K	0.697	0.929	0.733
C	0.693	0.867	0.722
F	0.667	0.619	0.656
A	0.628	0.426	0.522

Table 3. PPV, NPV, and Accuracy Values for Test Results versus GC/MS using HHS Cutoffs (All borderline results as negative)

Cocaine

Device	PPV	NPV	Accuracy
Perfect Device	1.000	1.000	1.000
C	1.000	0.667	0.856
H	1.000	0.591	0.800
B	1.000	0.578	0.789
M	0.966	0.774	0.900
A	0.963	0.667	0.844
I	0.953	0.511	0.722
Q	0.953	0.511	0.722
P	0.933	0.733	0.867
G	0.933	0.511	0.722
K	0.932	0.710	0.856
J	0.932	0.710	0.856
E	0.925	0.913	0.922
N	0.906	0.769	0.867
D	0.892	0.760	0.856
L	0.886	0.900	0.889

F	0.813	0.800	0.811

Table 4. PPV, NPV, and Accuracy Values for Test Results versus GC/MS using HHS Cutoffs (All borderline results as negative)

Opiates

Device	PPV	NPV	Accuracy
Perfect Device	1.000	1.000	1.000
B	0.481	0.968	0.820
J	0.464	0.968	0.811
E	0.341	0.980	0.689
I	0.325	0.960	0.678
Q	0.319	1.000	0.644
A	0.311	0.978	0.644
G	0.308	0.941	0.667
P	0.304	0.977	0.633
H	0.286	0.976	0.600
L	0.246	1.000	0.489
C	0.234	1.000	0.456
M	0.231	1.000	0.444
D	0.227	1.000	0.433
N	0.221	1.000	0.411
F	0.220	0.935	0.467
K	0.208	1.000	0.367

Table 5. PPV, NPV, and Accuracy Values for Test Results versus GC/MS using HHS Cutoffs (All borderline results as negative)

Phencyclidine

Device	PPV	NPV	Accuracy
Perfect Device	1.000	1.000	1.000

B	0.844	0.931	0.900
G	0.611	0.833	0.744
N	0.543	0.782	0.689
H	0.509	0.914	0.667
C	0.500	0.912	0.656
A	0.492	0.935	0.644
J	0.475	0.760	0.633
E	0.460	0.926	0.600
Q	0.437	1.000	0.556
F	0.429	0.794	0.567
K	0.424	0.875	0.544
L	0.423	0.947	0.533
D	0.419	1.000	0.522
I	0.413	1.000	0.511
P	0.411	0.941	0.511
M	N/A	N/A	N/A

Table 6. PPV, NPV, and Accuracy Values for Test Results versus GC/MS using HHS Cutoffs (All borderline results as negative)

All Drugs

Device	PPV	NPV	Accuracy
Perfect Device	1.000	1.000	1.000
J	0.717	0.822	0.778
B	0.699	0.798	0.757
G	0.673	0.810	0.749
E	0.642	0.830	0.735
H	0.629	0.774	0.709
M	0.611	0.767	0.689
N	0.597	0.797	0.693

A	0.591	0.798	0.689
P	0.569	0.734	0.658
Q	0.551	0.726	0.642
L	0.545	0.873	0.680
D	0.538	0.830	0.669
K	0.537	0.849	0.642
I	0.532	0.726	0.627
F	0.513	0.814	0.610
C	0.509	0.862	0.637

SAMHSA's **Workplace Resource Center** provides centralized access to information about drug-free workplaces and related topics.

U.S. Department of
Health and Human Services
Substance Abuse and Mental Health
Services Administration (SAMHSA)
www.samhsa.gov